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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/691,383	10/17/2000	Edwin F. Ullman	BEH-7381	3713

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EXAMINER
COOK, LISA V

ART UNIT	PAPER NUMBER
1641	6

DATE MAILED: 07/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/691,383	ULLMAN ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *1-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Amendment Entry

1. Applicant's response to the Office Action mailed 5 February 2003 is acknowledged (Paper No.7 filed 5/6/03). In amendment-A filed therein claim 19 and the specification have been modified. Currently, claims 1-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 5. Currently, claims 19-34 are under consideration.

OBJECTIONS MAINTAINED

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. For example see page 12. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner-on form PTO-892 or the applicant-on form PTO-1449 have cited the references they have not been considered.

3. The information disclosure statement (IDS) filed 3/6/091 in paper #2 has been considered as to the merits before First Action.

Applicants have not addressed the following objection. Accordingly it is maintained.

OBJECTIONS WITHDRAWN

Applicants have amended the disclosure to eliminate references to drawings, which were not filed and the utility of Trademarks. The objection to the specification below is withdrawn.

Specification

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

I. On page 4 of the disclosure a Brief Description of the drawings is included. However, no drawings are in the instant application. Appropriate correction required.

II. The use of the trademarks has been noted in this application. (.i.e. Tween on page 48 line 28). They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

The objection to the specification is withdrawn.

REJECTIONS WITHDRAWN

Claim Rejections - 35 USC § 112

5. Claims 19-34 stand withdrawn from rejection under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record on paper number 7. Applicants have clarified the claim deficiencies by amendment. Therein obviating the rejection.

Claim Rejections

6. With respect to the claim rejections 35 U.S.C. 103, Applicants amendment to claim 19 has initiated reconsideration of the previously cited art rejection. Applicant's amendment and arguments have been fully considered and found persuasive.

7. The following rejections are withdrawn:

I. Claims 19-20 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erb et al. (US Patent #6,251,688) and Erb et al. (US Patent #6,300,082) in view of Zhang et al. (The Journal of Biological Chemistry, 268 (14), May15, 1993, pages 10095-10101).

II. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erb et al. (US Patent #6,251,688) and Erb et al. (US Patent #6,300,082) in view of Zhang et al. (The Journal of Biological Chemistry, 268 (14), May15, 1993, pages 10095-10101)and further in view of Maggio (Immunoenzyme technique I, CRC press © 1980, pages 186-187).

III. Claims 27-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erb et al. (US Patent #6,251,688) and Erb et al. (US Patent #6,300,082) in view of Zhang et al. (The Journal of Biological Chemistry, 268 (14), May15, 1993, pages 10095-10101) and in further view of Zuk et al. (U.S.Patent#4,281,061).

NEW GROUNDS OF REJECTION NECESSITAED BY AMENDMENT

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 19-20 and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Oh et al. (US Patent #5,851,778) or Oh et al. (WO 89/03041).

In both the cited references Oh et al. employ a conjugate that comprises three moieties or members to evaluate specific binding partners. Two members of the conjugate are relatively small molecules (lees than about 7,000 Daltons). When the conjugate is bound by a macromolecular specific binding partner (sample drug –analyte), it sterically inhibits the binding of other/different macromolecules to another member of the three-member conjugate. See abstract of both references.

An assay protocol is outlined in figure 1 of both references. Therein an assay employing a tridentate complex (1st reagent) comprising biotin (first label), 1st hapten (drug analog), and 2nd hapten (small molecule) is mixed with a sample (free analyte – first hapten/drug), avidin (second label), antibody to the first hapten (antibody to the drug), and an antibody to the second hapten (antibody to the small molecule).

Examples of small molecule members are listed on page 29 – 1st paragraph (WO 89/03041) and column 13 line 65 through column 14 line 12 (US Patent #5,851,778). This list includes drugs, biotin, and dyes as recite in claim 20.

The binding interaction is evaluated using proximity labels (page 35 WO 89/0304 – column 16 US Patent 5,851,778), enzymes (page 36 WO 89/03041- column 17 US Patent #5,851,778), or donor-acceptor pairs (page 37 WO 89/03041 – column 18 US Patent#5,851,778).

Both references evaluate the signal from the target molecules as an increase over background or control signals (predetermined signals). See example 5 through example 7 (column 34 –column 39 US Patent #5,851,778 and pages 73-83 of WO 89/03041).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

II. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oh et al. (US Patent #5,851,778) or Oh et al. (WO 89/03041) in view of Maggio (Immunoenzyme technique I, CRC press © 1980, pages 186-187).

Oh et al. (US Patent #5,851,778) or Oh et al. (WO 89/03041) are set forth above.

Oh et al. (US Patent #5,851,778) or Oh et al. (WO 89/03041) differ from the instant invention in not specifically teaching the detection assay employing a solid phase such as particles.

However, Maggio disclose enzyme immunoassays wherein either the antigen or antibody is immobilized onto a solid phase. The solid phase can be particles, cellulose, polyacrylamide, agarose, discs, tubes, beads, or micro plates (micro titer plates). See page 186.

Oh et al. (US Patent #5,851,778) or Oh et al. (WO 89/03041) and Maggio are analogous art because they are from the same field of endeavor, all the inventions teach methods involving immunoassays.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use solid phase/particles as taught by Maggio in the assay method to detection the drugs interaction of Oh et al. (US Patent #5,851,778) or Oh et al. (WO 89/03041) because Maggio taught that solid phase assay systems employing particles/microplates/discs/tubes/beads "are very convenient to wash thereby reducing labor in assay procedures". Please see page 186.

III. Claims 27-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oh et al. (US Patent #5,851,778) or Oh et al. (WO 89/03041) in view of Zuk et al. (U.S.Patent#4,281,061).

The teachings of Oh et al. (US Patent #5,851,778) or Oh et al. (WO 89/03041) are set forth above. However, these references fail to teach the assay as a kit.

Zuk et al. (4,281,061) teach that "as a matter of convenience the reagents [of an immunoassay] can be provided as kits, where the reagents are in predetermined ratios, so as to substantially optimize the sensitivity of the assay in the range of interest" (column 22, lines 63-66).

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the detection assay as taught by Oh et al. (US Patent #5,851,778) or Oh et al. (WO 89/03041) because Zuk et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit. Further, the reagents in a kit are available in pre-measured amounts, which eliminates the variability that can occur when performing the assay. Although the reference does not specifically disclose that a kit would have instructions which teach how to use said kit, it would have been prima facie obvious to any one of ordinary skill in the art to include instructions which describe how to perform the assay. Applicants should note that the printed matter on the instructions in a kit cannot serve to define the kit over the prior art. See in re Gulack 217 USPQ (CAFC 1983).

9. For reasons aforementioned, no claims are allowed.

Response to Arguments

10. Applicant contends that the references of Erb et al. and Zhang et al. did not teach the instantly claimed invention. Further more, the combination of these references with Maggio or Zuk et al. did not cure the deficiencies. This argument was carefully considered and found persuasive. According the references of Oh et al. have been added to the rejections.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

12. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Lehnen (U.S. Patent #5,567,627) teach methods and reagents useful in the simultaneous and discrete analysis of multiple analytes.

B. Terstappen et al. (U.S. Patent #5,646,001) affinity-binding separation and release of one or more selected subset of biological entities from a mixed population thereof.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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7/10/03

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